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EXAMINER

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/807,810
Filing Date: July 10, 2001
Appellant(s): MC INTOSH ET AL.

Raymond J. Lillie
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 2/02/06 appealing
from the Office action mailed 9/10/04.

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(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The Examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The Appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

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(6) Grounds of Rejection to be Reviewed on Appeal

The Appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Soiffer, R.J., et al. Blood. 15 April 1997;89(8):3039-3047, see particularly page 3040, *Treatment protocol*.

Donnelly, J.J., et al. Exp. Eye Res. 1993;56:157-165, see particularly the Abstract.

5,736,396, Bruder, S.P., et al. 07 April 1998, see particularly column 4, lines 41-45.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1, 2, 4, 5, 8, 9, 11-13, 16, 17, 19, 21, 24, 26-28, 30, and 32 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Soiffer et al. (1997), as evidenced by U.S. Patent No. 5,736,396 (1998).

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Soiffer et al. teaches a method of inducing a reduced immune response to donor tissue in a bone marrow transplant (BMT) recipient, or reducing an immune response against recipient tissue by donor tissue, or treating a transplant recipient for graft versus host disease, comprising treating (or contacting) the recipient with allogeneic (donor derived) fibroblasts and immunosuppressive agents (see particularly, page 3040, *Treatment protocol*). Note that the '396 patent merely establishes that bone marrow includes fibroblasts (see column 4, lines 41-45), thus, any BMT recipient would also receive donor derived fibroblasts. Further note that the phrase reciting "in an amount effective to reduce an immune response" does not comprise an actual limitation as no threshold amount of fibroblasts has been established, thus, the small number of fibroblasts in bone marrow would reduce the immune response some small amount. Additionally, the intention of treatment, "to treat rejection" (Claim 11) also fails to comprise an actual limitation.

The reference clearly anticipates the claimed invention.

Claims 6, 7, 10, 20, 22, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soiffer et al. in view of Donnelly et al. (1993, IDS).

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Soiffer et al. has been discussed above.

The reference teaching differs from the claimed invention only in that it does not teach the use of fibroblasts allogeneic to both the transplant donor and the recipient nor does it teach various different times of administration of said fibroblasts, i.e., before, during, or after BMT.

Donnelly et al. teaches that fibroblasts are immunosuppressive, interfere with lymphocyte activation, and interfere with alloimmune responses (see particularly the abstract).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to perform the BMT method of Soiffer et al. including additional fibroblasts. One of ordinary skill in the art at the time the invention was made would have been motivated to include said additional fibroblasts given the teachings of Donnelly et al. that fibroblasts are immunosuppressive, interfere with lymphocyte activation, and interfere with alloimmune responses. Note that as there are only 3 possible types/sources of fibroblasts, autologous to the recipient, autologous to the donor, or allogeneic to both, the choice of any convenient source would be obvious. Also note that the timing of administration, i.e., administration of the fibroblasts before,

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during, or after transplantation comprises only routine optimization that would fall well within the purview of one of skill in the art at the time of the invention.

(10) Response to Argument

Rejection under 35 U.S.C. 102(b):

Appellant argues "Soiffer, however, does not disclose or even remotely suggest to one of ordinary skill in the art a method of inducing a reduced immune response to donor tissue, or a method of reducing an immune response against recipient tissue by donor tissue, of a method of treating a transplant recipient for graft versus host disease by administering isolated fibroblasts or a supernatant from an isolated fibroblast culture".

Appellant's argument may be true, however, the method of the instant claims has been performed in the prior art. As it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure, the method of the instant claims is not patentably distinct. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). See also In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991), "Granting a patent on the discovery of an unknown but inherent

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function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art".

Appellant argues, "It is clear that from reading the specification, that when Applicants refer to isolated fibroblasts, they do not mean fibroblasts that merely are removed from the donor's bone or any other tissue where fibroblasts may be present".

It is the Examiner's position that neither the specification, nor ordinary meanings of "isolated" support the appellant's argument. First, the specification makes clear that no limitations are to be derived from the disclosure of the specification:

"It should be understood that the methods described herein may be carried out in a number of ways and with various modifications and permutations thereof that are well known in the art. It may also be appreciated that any theories set forth as to modes of action or interactions between cell types should not be considered as limiting this invention in any manner, but are presented such that the methods of the invention can be more fully understood."

"The following examples further illustrate aspects of the present invention. However, they are in no way a limitation of the teachings or disclosure of the present invention as set forth herein." (page 10).

The specification also discloses "The fibroblasts can also be administered to the recipient as part of the transplant" (page 3).

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It appears then that Appellant is now trying to read limitations into the claims that are not supported by the specification. Second, as set forth in the Final Action of 9/10/04, "isolated" can "be defined as separated or detached, thus, the fibroblasts need not be purified but only separated from their original source, i.e., the donor's bone. Accordingly, the reference still teaches the method of the instant claims."

Appellant argues, "contrary to the Examiner's assumptions and assertions, the fibroblasts need not be isolated solely from bone marrow".

The Examiner has made no such assumptions nor assertions. It is merely the Examiner's position that a bone marrow comprises fibroblasts, thus, the transplant of bone marrow meets the limitations of the claims.

Rejection under 35 U.S.C. 103(a):

Appellant summarizes the references and concludes, "The combination of Soiffer and Donnelly, therefore, does not even remotely suggest to one of ordinary skill in the art that one may administer isolated fibroblasts or a supernatant from an isolated fibroblast culture, in order to induce a reduced immune response against donor tissue, to reduce an immune response against recipient tissue by donor tissue, or to treat a transplant recipient for graft versus host disease".

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As set forth in the rejection, it remains the Examiner's position that, given the teachings of Donnelly et al. that fibroblasts are inherently immunosuppressive, it would have been obvious to include them in the method of Soiffer et al.


(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the Examiner in the Related Appeals and Interferences section of this Examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.


Respectfully submitted,

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3/28/04
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